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No. 03-1499

# In The Supreme Court of the United States

HALIA S. MARSH, Executrix of the estate of Robert Sidney Marsh, THEODORE C. McLEOD, Executor of the Estate of Beulah McLeod, and THOMAS R. SPEER,

*Petitioners,*

v.

W.R. GRACE & CO., FRIT INDUSTRIES, INCORPORATED, and CONTINENTAL CASUALTY COMPANY,

*Respondents.*

**On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit**

## BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

1. Whether the Court of Appeals properly affirmed the District Court's discretionary exclusion of the Petitioners' expert witness testimony on the issue of proximate cause pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), and its subsequent grant of Summary Judgment in favor of Respondents.

2. Whether the Court of Appeals properly affirmed the District Court's discretionary denial of Petitioners' motions to amend their Complaints where the District Court found that the motions were unduly delayed and the proposed amendments would have been unfairly prejudicial.

## CORPORATE DISCLOSURE STATEMENT

Respondent W. R. Grace & Co. has no parent corporations. No publicly traded corporations own more than 10% of the outstanding stock of W. R. Grace & Co.

Respondent Frit Industries, Incorporated has no parent corporations. No publicly traded corporations own more than 10% of the outstanding stock of Frit Industries, Incorporated.

Respondent Continental Casualty Company is a subsidiary of CNA Financial Corporation. CNA Financial Corporation is a publicly traded stock on the New York Stock Exchange, and it owns more than 10% of the outstanding stock of Respondent Continental Casualty Company. No other publicly traded corporations own more than 10% of the outstanding stock of Continental Casualty Company.

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## OPINIONS AND ORDERS BELOW

The District Court's Judgment and Memorandum Opinion below, *Marsh v. W.R. Grace & Co.*, No. 3:90CV00613 (M.D.N.C. May 26, 1998), were not chosen for publication in the Federal Supplement, however, they have been reprinted in the Supplemental Appendix to the Petition at A-1 and A-3 respectively. The Fourth Circuit's Opinion below was not chosen for publication in the Federal Reporter; however the opinion, *Marsh v. W. R. Grace & Co.*, No. 98-1943, Prod. Liab. Rep. (CCH) ¶ 16,803 (4th Cir. November 19, 2003), has been reprinted in the Appendix to the Petition at A-1. Finally, the Fourth Circuit's Order denying Petitioners' Petition for Rehearing and Rehearing En Banc below was not chosen for publication in the Federal Reporter; however, the Order, *Marsh v. W. R. Grace & Co.*, No. 98-1943 (4th Cir. December 17, 2003) (order denying rehearing), has been reprinted in the Appendix to the Petition at A-12.

## STATEMENT OF JURISDICTION

Each of these three cases, prior to consolidation by the United States District Court for judgment, were originally filed in the General Court of Justice, Superior Court Division, Moore County, North Carolina. Each action was timely removed to the United States District Court for the Middle District of North Carolina pursuant to 28 U.S.C. §§ 1441 and 1446. Jurisdiction in the District Court was

based upon diversity of citizenship pursuant to 28 U.S.C. § 1332. (J.A. at 26-28, 1184-1187, 2507-2510.)[1]

Summary judgment as to all claims in these three cases was entered simultaneously on May 26, 1998. *Marsh*, No. 3:90CV00613. (Supp. App. at A-2.) Notices of Appeal were timely filed on June 25, 1998. (J.A. at 1165-1167, 2484-2486, 2895-2897.) Appellate jurisdiction of the United States Court of Appeals for the Fourth Circuit was based upon 28 U.S.C. § 1291. (*Id.*)

On November 19, 2003, the Fourth Circuit entered its Opinion affirming the Judgment of the District Court. *Marsh*, No. 98-1943. (App. at A-1.) On December 17, 2003, the Clerk of Court for the Fourth Circuit entered an Order denying Petitioners' Petition for Rehearing and Rehearing En Banc. *Marsh*, No. 98-1943 (order denying rehearing). (App. at A-12.) Petitioners filed their Petition for Writ of Certiorari pursuant to 28 U.S.C. § 1254(1) on March 16, 2003, within 90 days of the denial of their Petition for Rehearing.

## RULES INVOLVED IN THIS CASE

Federal Rules of Evidence

Rule 104. PRELIMINARY QUESTIONS

(a) Questions of Admissibility Generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a

[1] Citations to "J.A." are made to the Joint Appendix submitted to the Fourth Circuit.

privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy Conditioned on Fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) Hearing of Jury. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on other preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

Rule 702. TESTIMONY BY EXPERTS

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.[2]

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[2] Rule 702 of the Federal Rules of Evidence was amended April 17, 2000, effective December 1, 2000 to include the following language after the word "otherwise" at the end of the rule as reprinted here: "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

Federal Rules of Civil Procedure

Rule 15. AMENDED AND SUPPLEMENTAL PLEADINGS

> A party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served or, if the pleading is one to which no responsive pleading is permitted and the action has not been placed upon the trial calendar, the party may so amend it at any time within 20 days after it is served. Otherwise a party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires.

## STATEMENT OF THE CASE

Petitioners Halia S. Marsh, Executrix of the Estate of Robert Sidney Marsh ("Marsh"), Theodore McLeod, Executor of the estate of Beulah M. McLeod ("McLeod"), and Thomas R. Speer ("Speer")[3] brought separate actions against Respondents alleging that each of them contracted a different form of cancer allegedly due to the alleged exposure to traces of picloram allegedly found in fertilizer, known as "Gold Dollar," that was applied to their tobacco and vegetable crops in 1984. Picloram is a common broadleaf herbicide. The Gold Dollar fertilizer was manufactured by Respondent W.R. Grace & Co. ("Grace") and

[3] For the convenience of the Court, this brief will refer to Mrs. Marsh, Mr. McLeod, and Mr. Speer collectively as "Petitioners."

contained micronutrients manufactured by Respondent Frit Industries, Inc. ("Frit"). Respondent Continental Casualty Company provided insurance services to Grace. Petitioners' alleged claims against Respondents for civil conspiracy, failure to warn, false representations, negligence, breach of express and implied warranties, and unfair settlement practices. The Marsh Complaint was filed on or about October 16, 1990; the McLeod and Speer Complaints were filed on or about December 21, 1990.

On October 24 and October 28, 1991, after engaging in extensive discovery, each of the Respondents moved for summary judgment in the Marsh case on the grounds, among others, that the Plaintiff could not show that the alleged exposure to picloram proximately caused her husband's cancer. (J.A. at 145-147.) In November 1994, after further discovery, Respondents moved for summary judgment in the McLeod and Speer cases also challenging the Plaintiffs' evidence of proximate cause. (*Id.* at 2157-58.) On May 26, 1998, the District Court granted Respondents' motions for Summary Judgment in all three cases by way of one consolidated Memorandum Opinion and Judgment. (Supp. App. at A-2.)

## STATEMENT OF FACTS

### A. The Petitioners' Allegations.

In 1984, Marsh and McLeod purchased Gold Dollar fertilizer from Roy Burt Enterprises, Inc. (J.A. at 70, 1199, 2597.) The fertilizer was used on tobacco crops and small vegetable gardens. Petitioners allege that they were each exposed to picloram, a commonly used herbicide, which

they further allege was present in the Gold Dollar fertilizer, was a human carcinogen, and caused each of them to suffer a different form of cancer.

Marsh worked on a farm owned by his son, Waymon Marsh (the "Marsh Farm"). In October 1988 Marsh, at the age of 78, was diagnosed with lung cancer. (*Id.* at 87, 100.) At the time he was diagnosed, Marsh was found to have a 5 cm tumor in his lungs that had metastasized to his spine. (*Id.* at 87.) Marsh had smoked cigarettes for more than 50 years and had been exposed to numerous chemicals during his life as a farmer. (*Id.* at 88, 100.)

McLeod worked on a tobacco farm that she owned with her husband (the "McLeod Farm"). In August 1986, McLeod, at the age of 74, was diagnosed with cervical cancer, one of the most prevalent female cancers. (*Id.* at 2192-93.) A diagnostic workup revealed an I-B carcinoma of the cervix of approximately four to five centimeters in size. (*Id.* at 2224.) As with Marsh, McLeod had been exposed to numerous chemicals in her adult life while assisting her husband on their farm. (*Id.* at 2183-84, 2197.)

Speer worked on the Marsh farm and had also worked as an auto-body mechanic. In February 1986, at the age of 63, Speer complained of rectal bleeding during a regular check-up. The bleeding continued through 1987. (*Id.* at 2656.) A colonoscopy revealed a 2.7 cm colorectal tumor. Speer had a family history of colorectal cancer, which significantly increased his risk of developing the disease. (*Id.* at 2746.) As with both Marsh and McLeod, Speer had been exposed to numerous chemicals during his life. (*Id.* at 1452-55.)

**B. The Alleged Presence of and Exposure to Picloram.**

During the summer of 1984, various tobacco farmers throughout middle and eastern North Carolina, southern Virginia, and northern South Carolina noticed deformed leaves in tobacco fertilized with Gold Dollar. Upon learning of these problems, Grace undertook an investigation to determine the source of the leaf deformities. Not every farmer who purchased Gold Dollar experienced abnormal tobacco growth, and even on farms where deformities were present, they did not occur with uniformity. (*Id.* at 152, 187, 2161, 2168, 2549, 2586.)

In October 1984, Dr. A. D. Worsham of North Carolina State University conducted plant bioassays using numerous samples of materials collected under the direction of Dr. Daniel Simpson on behalf of Grace.[4] (*Id.* at 152-156, 2161-2165, 2579-2583.) Two-thirds of the plant bioassays of Gold Dollar did not reveal the presence of any herbicide. Of those bioassays that did detect the presence of herbicide, the bioassays did not, and could not, identify which particular herbicide, including picloram, was affecting the plants. (*Id.* at 153, 2162-64, 2580-82.)

The North Carolina Department of Agriculture also conducted a series of tests to determine the source of the leaf deformities by testing 62 different samples of Grace fertilizer by gas chromatography. Some of these tests did not detect the presence of any herbicide. Of those tests

[4] A bioassay is a test to determine the effect of a substance on a living thing, such as, in this case, tobacco. The bioassay test grew plants under controlled, scientific conditions.

that did detect herbicide, some detected dicamba and others detected picloram. (*Id.* at 186-87, 2167-68, 2585-86.)

Four independent laboratories performed gas chromatography and/or mass spectrometry on the samples to detect the presence of herbicides. In total, these laboratories performed 1,238 gas chromatographs. More than two-thirds of these tests did not detect the presence of any herbicides. Of those tests that did detect the presence of herbicide, different herbicides were detected including dicamba, 2,4-D, and picloram. (*Id.*)

The Gold Dollar fertilizer actually purchased and used on the Marsh and McLeod farms was never chemically tested to determine if it contained any herbicide, including picloram. Scientific tests of material from the Marsh farm, but not the McLeod farm, were conducted in 1985, 1987, and 1988. None of these tests indicated the presence of picloram. (*Id.* at 187-92.) No scientific tests indicate the presence of picloram in the fertilizer used on Petitioners' farms where they worked or in their gardens. (*Id.* at 93-98, 121-36, 186-93, 2632-40.)[6]

[6] The only evidence Petitioners presented to the District Court that the fertilizer used on the Marsh farm contained picloram consisted of the testimony of Benjamin Kittrell and Monroe Enzore who opined that the tobacco appeared to have been exposed to picloram based on photographs that were taken some time after 1984 and an examination of the crop in 1991. The Kittrell affidavits appear to have been reprinted, without any discussion, in the place of the Petitioners' Statement of Facts in their Petition. No similar evidence was submitted with regards to the McLeod farm.

### C. The Expert Evidence Regarding Picloram.

Petitioners designated Dr. Alan S. Levin, M.D. ("Levin") as their sole expert witness with regard to the issue of whether picloram is a human carcinogen and if so whether exposure to picloram caused their specific cancers. (*Id.* at 435-67, 1231-2156.) The District Court properly found Levin's opinions to be inherently unreliable. They lack scientific methodology and are objectively unverifiable. Rather than determining if picloram was capable of causing a particular, site-specific cancer in humans and then determining whether each Petitioner was exposed to a sufficient dose of picloram to have caused his or her particular cancer, Levin reasoned in reverse. He relied upon the conclusion that Petitioners had cancer and *assumed* that it was caused by picloram. He admitted in his own testimony that he did not rule out alternative causes of the Petitioners' cancers:

> Q. How or did you rule out that alternative causes for this cancer?
>
> A. Alternative causes? I don't know that I ruled anything out. I opined that picloram was the cause or a cause of the cancer. But I didn't rule out other etiology.

(*Id.* at 1577.)

By contrast, in support of their motions for Summary Judgment, Respondents submitted the Joint Affidavit of Drs. Philip S. Guzelian, Robert C. James, and Gregory Smith. (*Id.* at 133-314, 2176-2308, 2647-2843.) At the time of the joint affidavit submitted to the District Court, Dr. Guzelian was a Professor of Medicine at the University of Colorado Health Sciences Center in Denver, Colorado who

also served as the Chief of the Section of Medical Toxicology and Co-Director of the Hepatobiliary Research Center. Dr. James was a toxicologist and research scientist employed as an Associate Professor in the Center for Environmental Toxicology at the University of Florida, Gainesville and as an Adjunct Professor at Florida State University and the Medical College of Wisconsin. Dr. Smith was a medical doctor and a senior medical epidemiologist in the Environmental Epidemiology Section, North Carolina Department of Environment, Heath, and Natural Resources.

In the Joint Affidavit, Respondents' experts described the scientific method for determining, to a reasonable degree of medical and scientific certainty, whether picloram caused the Petitioners' cancers as follows:

> (1) There must be convincing evidence that the chemical in question is capable of producing the alleged disease in humans [Toxicity];
>
> (2) There must be convincing evidence that the dose of the chemical received by the person exposed was of sufficient magnitude to have been capable of producing the alleged disease [Dose-Response];
>
> (3) There must be convincing evidence that the chemical exposure was temporally related to the onset of the disease [Temporality];
>
> (4) There must be a sufficient basis for carrying out a differential diagnosis, excluding other possible confounding or contributing etiologies that might have caused the alleged disease [Elimination of Confounders];

> (5) There must be scientific data which explains how the chemical produces the alleged effect on a cellular and biochemical level [Biological Plausibility].

(*Id.* at 206-07, 2185-86, 2657-58.) Applying this scientific methodology to the evidence in each of the Petitioners' cases, the Joint Affiants concluded, to a reasonable degree of medical and scientific certainty, that, among other things, Petitioners' evidence fails to show that their cancers resulted from the alleged exposure to picloram. (*Id.* at 259, 2197, 2669.)

The Joint Affiants concluded that picloram was not a carcinogen and thus cannot pass the toxicity inquiry described above. (*Id.* at 2209, 2684.) This conclusion is based upon substantial evidence that picloram is not carcinogenic. For example, the Environmental Protection Agency ("EPA") has never classified picloram as carcinogenic. In fact, the EPA considers 500 parts per billion an acceptable level of picloram in drinking water. (*Id.* at 219-21, 1216-17, 2210-20.) Similar regulations exist establishing safe levels of picloram in food commodities promulgated by the Office of Pesticide Programs, Office of Pesticide and Toxic Substances. *See, e.g.*, 40 C.F.R. § 180.292 (1999). In addition, an epidemiologic study followed a group of 141 Dow Chemical Company employees who were regularly exposed to one million times greater amounts of picloram than that to which the Petitioners hypothetically could have been exposed. (*Id.* at 162, 210, 2188-89, 2203-04, 2679.) That study found no site-specific cases of cancer deaths. Two animal bioassays conducted by the National Cancer Institute specifically

designed to determine the carcinogenic potential of picloram also demonstrated that picloram is not carcinogenic. (J.A. 1216-19, 2203, 2205, 2206, 2678, 2681, 2573-75.)

In addition to finding that picloram is not carcinogenic, the Joint Affiants specifically addressed the potential for other causes of Petitioners' cancers. They opined that Marsh's lung cancer was far more likely caused by his 52 years of cigarette smoking than his exposure to fertilizer in 1984. (*Id.* at 226-28.) Likewise, McLeod's cervical cancer is one of the most prevalent female cancers in the world, the most common cause of which is viral infection, not environmental chemical exposure. (*Id.* at 2193-94.) Finally, Speer's colorectal cancer is also one of the most common forms of cancer in the United States, and Speer's family history of that specific cancer suggested that he probably had a genetic predisposition to developing it. (*Id.* at 2665-66.)

Respondents' Joint Affiants further addressed the Toxicity, Dose-Response, Temporality, and Biological Plausibility inquiries outlined above. In each case, the Joint Affiants concluded that there was no connection between picloram and the Petitioners' cancers. (*Id.* at 2209, 2684 (Toxicity), 216-19, 219-20, 2685-90 (Dose-Response), 222-25, 2192-93, 2664-65 (Temporality), 225-31, 2195-97, 2666-69 (Biological Plausibility).)

## REASONS FOR DENYING THE PETITION

The Petitioners' nearly incomprehensible Petition for Writ of Certiorari appears to attempt to raise four questions to be presented for review before the Supreme Court. Two of the questions presented do not arise from the

holding of the Fourth Circuit below. Petitioners appear to request a Writ of Mandamus, without calling it as such, commanding a "ruling on Plaintiffs' Rule 60 Motion," which, according to the Petition, was filed after the Notice of Appeal had been made "to point out errors in the Trial Court Decision." (Pet. at 11-12.) Petitioners also seek review of whether the District Court erred by failing to enter a Pretrial Scheduling Order in some, but not all, of the cases, an allegation of error not raised before the Fourth Circuit and which has no connection whatsoever with the Fourth Circuit's Opinion or to the critical issue of whether a grant of summary judgment was appropriate.

The two remaining questions presented framed by Petitioners relate to the admissibility of Dr. Levin's testimony. The first question presented poses, in more general terms, whether the District Court erred in granting summary judgment and suggests that the Fourth Circuit may have violated the principles of *Foman v. Davis*, 371 U.S. 178, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962) and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). No specific discussion of either *Daubert* or *Foman* is made in the Petition, so it is unclear exactly what the alleged error committed by the Fourth Circuit may be. *Foman* appears to be cited for the proposition that Petitioners challenge the denial of their motions to amend their respective Complaints. *Daubert* appears to have been cited for the proposition that Petitioners challenge the exclusion of their expert, Dr. Levin, which resulted in the grant of summary judgment. The remaining question presented appears to suggest that there may be a conflict between the First Circuit Court of Appeal and the Fourth Circuit Court of Appeal regarding the admissibility of Dr. Levin's testimony.

A simple examination of the record below and the Opinion of the Fourth Circuit reveals that there are no compelling reasons for the Supreme Court of the United States to grant a Writ of Certiorari in this matter. The central inquiry regarding the admissibility of Dr. Levin's testimony is nothing more than an unexceptional examination of the admissibility of a proposed expert's testimony – an examination performed by the trial court to which appellate courts give great deference. Likewise, the denial of a motion to amend pleadings is a decision placed squarely within the discretion of the trial court. The cases present nothing novel or unique. Most importantly, however, the Court should not grant a Writ of Certiorari because the Fourth Circuit did not err in affirming the decision of the District Court.

## I. NO COMPELLING REASON EXISTS TO REVIEW THE ACTION OF THE COURT OF APPEALS

Rule 10 of the Rules of the Supreme Court outlines exemplary considerations in the evaluation of whether a Writ of Certiorari should issue in a particular case. While the examples provided are merely illustrative, the Rule is clear in its expectation that a Writ of Certiorari should issue only "for compelling reasons." Sup. Ct. R. 10. There are no compelling reasons for a Writ of Certiorari to issue in the case at bar. Nothing in the Fourth Circuit's Opinion below conflicts with the decisions of this Court or any other Court of Appeal. The opinion does not address any novel or important federal questions. Nothing regarding the content of the opinion or the procedure on appeal could be construed as a departure from the accepted and usual course of judicial proceedings. The Opinion of the Fourth Circuit below correctly stated and applied simple rules that previously have been addressed by this Court in detail and consistently and regularly applied by

Courts across the United States. Nothing in the Petition suggests that the Court should consider a reversal or change in the existing law, and the Petition fails to demonstrate any error on the part of the Fourth Circuit.

**1. The District Court properly excluded Dr. Levin's testimony.**

In reviewing the District Court's grant of Summary Judgment, the Fourth Circuit recognized that the standard of review was *de novo*. *Marsh*, No. 98-1943 slip op. at 5, *citing*, *Metropolitan Life Ins. Co. v. Pettit*, 164 F.3d 857, 860 (4th Cir. 1998). (App. at A-5.) In conducting its review, all facts as found by the District Court were taken in the light most favorable to the Petitioners. *Marsh*, No. 98-1943 slip op. at 5, *citing*, *Beall v. Abbott Lab.*, 130 F.3d 614, 618-619 (4th Cir. 1997). (App. at A-3.) In viewing the case in this light, the Fourth Circuit assumed, as the District Court did as well, that the Gold Dollar fertilizer sold by Grace did in fact contain picloram, *Marsh*, No. 98-1943 slip op. at 3 (App. at A-3.); *Marsh*, No. 3:90CV00613 (Supp. App. at A-5.), despite evidence that picloram was never specifically found on the Petitioners' farms and studies which indicated that not all Gold Dollar fertilizer contained herbicides of any kind (J.A. 153, 186-92, 2162-64, 2167-68, 2580-82, 2585-86). The Fourth Circuit also assumed, just as the District Court did, that the Petitioners themselves were actually exposed to picloram through handling of the fertilizer, by eating vegetables grown with the fertilizer, and by consuming fish caught in a pond located near fields where the fertilizer was used, *Marsh*, No. 98-1943 slip op. at 3 (App. at A-3.); *Marsh*, No. 3:90CV00613 (Supp. App. at A-5.), despite the lack of evidence that the Petitioners themselves were actually

exposed to picloram (J.A. at 93-98, 121-36, 186-93, 2632-40).

The District Court held that because the Petitioners all claimed that their sole damages were the cancers they suffered, a case-dispositive issue in all cases was whether there was any evidence that the Petitioners' cancers were proximately caused by exposure to picloram. *Marsh*, No. 98-1943 slip op. at 5 (App. at A-5); *Marsh*, No. 3:90CV00613 (Supp. App. at A-6.). Both the Fourth Circuit and the District Court recognized that the sole evidence presented to the District Court by the Petitioners on the issue of proximate cause was the testimony of Dr. Levin. *Id.* Under both the Fourth Circuit and District Court's analyses, the issue of whether summary judgment in favor of the Respondents was proper therefore turned on the District Court's decision to exclude Levin's testimony.

A District Court's decision to admit or exclude expert testimony is reviewed under an abuse of discretion standard. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997). This follows the Supreme Court's admonition that trial courts be provided "considerable leeway" in exercising their duty under Rule 104 of the Federal Rules of Evidence to evaluate the admissibility of evidence proposed under Rule 702. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156, 119 S. Ct. 1167, 1178, 143 L. Ed. 2d 238 (1999). Accordingly, the Fourth Circuit was charged with the duty to examine the record before it and reverse the decision of the District Court only if the District Court made a clear error in judgment. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999).

The critical analysis performed by the District Court in assessing Levin's testimony was grounded in Rule 702 of the Federal Rules of Evidence as explained in *Daubert*. Rule 702 plainly states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

In *Daubert*, this Court analyzed the requirements of Rule 702 with specific attention to the issue of how a Court should determine whether a proposed expert should be permitted to testify under the rule. Under *Daubert*, the District Court must make a "preliminary assessment [1] of whether the reasoning or methodology underlying [the proposed expert] testimony is scientifically valid and [2] of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-593, 113 S. Ct. at 2796. In other words, the trial court is vested with the responsibility of determining, before any testimony of the expert is considered, whether the expert's methods are reliable and whether the testimony would be helpful to the jury to determine a fact in issue. The Fourth Circuit limited its consideration of Levin's testimony to the reliability inquiry required by *Daubert* since there was no dispute that the testimony was relevant to the issue of proximate cause. *See Marsh*, No. 98-1943 slip op. at 6 (App. at A-5).

To assist trial courts in deciding whether proposed testimony is sufficiently reliable to pass muster under Rule 702, *Daubert* provided four examples of ways in which the reliability of a particular method can be assessed: (1) that the method is capable of being tested and has been tested, (2) that the method is subjected to peer review and publication, (3) that the method has a known or knowable rate of error, and (4) that the method has attained general acceptance in the pertinent scientific community. *See Daubert*, 509 U.S. at 593-94, 113 S. Ct. at 2796-97. Both the District Court herein and the Fourth Circuit recognized the *Daubert* factors and applied them to the factual record before them. *See Marsh*, No. 98-1943 at slip op. at 6-9 (App. at A-6-A-9); *Marsh,* No. 3:90CV00613 (Supp. App. at A-7-A-15).

The Fourth Circuit held that the District Court did not abuse its discretion in excluding Levin's testimony. *See Marsh*, No. 98-1943 at slip op. at 6-9. In affirming the District Court's decision, the Fourth Circuit observed that (1) Levin's testimony was not subject to testing because Levin started with the conclusion that picloram caused the Petitioners' cancers and then generated a hypothesis to support his conclusion, (2) the only laboratory test relied upon by Levin did not identify the specific agent that caused the Petitioners' cancers, (3) Levin failed to rule out any alternative causes for the Petitioners' cancers, (4) Levin's assertion that picloram is a carcinogen is inapposite to much of the scientific literature available, (5) Levin's inability to determine the minimum exposure to picloram necessary to cause cancer created an unacceptable potential for error, and (6) Levin's methods are not generally accepted by the medical community. *See id.*

Levin's theory of disease is based upon the premise that the host is predisposed to the disease:

> The key here is that all disease is a function of the host, not of the etiologic agents, and if the host is set up to get cancer, then the etiologic agent can [cause] cancer. Then, on the other hand, if the host is set up to get lupus, then the etiologic agent can cause lupus.

(J.A. at 1521.)

Levin's analysis completely ignores the level of exposure to an alleged cancer-causing agent and the temporal relationship between the alleged exposure and the onset of the tumor. In his own words, "it is reasonable to *presume* that the exposure to a known carcinogen will cause cancer in an individual who develops cancer after an individual is exposed to that [carcinogen]." (*Id.* at 1835) (Emphasis added). In stating this presumption, Levin assumes, without demonstrating, that picloram is itself a cancer-causing agent and that Petitioners were not exposed to any other cancer-causing agents.

Both the District Court and the Fourth Circuit strictly followed the analysis of *Daubert*. The Petitioners point to no example of any failure of the District Court or the Fourth Circuit to properly analyze Levin's testimony in light of Rule 702, *Daubert* or any other case concerning the admissibility of expert witness testimony. The bulk of the Petition for Writ of Certiorari is composed of unconnected quotes and citations to medical journals and affidavits that have no bearing on the issues decided by the Fourth Circuit. Petitioners complain that the Affidavits of Benjamin Kittrell, reprinted as the "Statement of Facts" in the Petition, were not allowed by the District Court; however,

nothing in the Kittrell Affidavits is related to the consideration of Levin's methodology or the reliability of his opinions. Furthermore, Kittrell's affidavits do not address the critical issue of whether picloram proximately caused Petitioners' cancers.

Portions of the Petition appear to suggest that a District Court Judge in the First Circuit had already ruled that Levin was a reliable expert witness; therefore, the refusal of the District Court herein to allow Levin to testify indicates a conflict between the First and Fourth Circuits. It does not appear, from the content of the Petition, that Petitioners allege that the Fourth Circuit has adopted a standard different from *Daubert* in the evaluation of the reliability of expert witness testimony, nor does it appear that the Petitioners allege that the First and Fourth Circuits have established different and opposing views of *Daubert*. The suggestion is that merely because one District Court judge allowed Levin to testify that the District Court herein was somehow controlled by that decision.

Nothing in *Daubert* suggests that an expert allowed by one court for one purpose must therefore be allowed by all courts in all cases. Such a holding would divest trial courts of the discretion purportedly granted to them under this Court's opinions in *General Elec.*, *supra*, and *Kumho Tire*, *supra*. The District Court's application of the principles outlined in *Daubert* is consistent with this Court's prior holdings regarding the obligation of the trial court to ensure that expert witness testimony is inherently reliable. The Fourth Circuit's careful and deliberate consideration of the District Court's actions and the record below was consistent with the Rules of Evidence and the decisions of this Court. The District Court properly applied the

teachings of this Court and the subsequent appellate decisions in this area, and the Fourth Circuit properly reviewed the decision of the District Court. Accordingly, there is no reason to grant the Petition.

Nevertheless, the only case within the First Circuit that Respondents have been able to locate that even refers to "Dr. Alan S. Levin" is a District Court memorandum in the case of *Anderson v. W. R. Grace & Co.*, 628 F. Supp. 1219 (D. Mass. 1986), decided seven years before this Court's decision in *Daubert*. *Anderson* involved a series of claims made by and on behalf of children who suffered leukemia allegedly due to exposure to contaminated water. The case does not involve picloram, dicamba, or 2,4-D, nor does it appear to involve lung cancer, cervical cancer, or colorectal cancer. In addition, *Anderson* does not address the admissibility of Levin's testimony, much less the admissibility of his testimony under *Daubert*. Moreover, *Daubert* has been recognized and applied in the First Circuit under the same analytical framework outlined above, *See U.S. v. Diaz*, 300 F.3d 66 (1st Cir. 2002). Because *Anderson* does not address the admissibility of Levin's testimony, and because it was a District Court decision and not an appellate court decision, there is no conflict among the circuits that would necessitate this Court's intervention on a Petition for Certiorari.

**2. The District Court did not abuse its discretion in denying Petitioners' motions to amend their Complaints.**

Marsh moved to amend her complaint pursuant to Rule 15(a) of the Federal Rules of Civil Procedure in March 1992 after extensive discovery had already been completed. The proposed amendment would have changed

Marsh's theory of the case to allege that her decedent's cancer was caused by chemicals other than picloram. The District Court denied Marsh's motion on the grounds that she had unduly delayed making the motion and it would be unfairly prejudicial to the defendants. An identical motion was made in the Speer case in October 1994, and it was denied by the District Court for the same reasons. The Fourth Circuit affirmed the District Court's ruling on both counts. *Marsh*, No. 98-1943 at slip op. at 9, 10 (App. at A-9-A-10.)

Although Rule 15 of the Federal Rules of Civil Procedure provides that leave to amend "shall be freely given when justice so requires," Fed. R. Civ. Pro. 15, courts have consistently held that a motion to amend should be made as soon as the necessity for altering the pleading becomes apparent, *See Deasy v. Hill*, 833 F.2d 38, 41 (4th Cir. 1987), *cert. denied*, 484 U.S. 977, 108 S. Ct. 1271, 99 L. Ed. 2d 483 (1988). Leave to amend will be denied if the amendment is sought with undue delay or bad faith, if it is sought only as a dilatory motive, or if it would prejudice the opposing party. *See Island Creek Coal Co. v. Lake Shore, Inc.*, 832 F.2d 274, 279 (4th Cir. 1987). Furthermore, a motion to amend will be denied when the proposed amendment would be futile or would belatedly add claims that change the character of the litigation. *See Shealey v. Winston*, 833 F.2d 1009 (4th Cir. 1991); *Deasy, supra*; *See also Lonestar Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc.*, 43 F.3d 922 (4th Cir. 1995) (affirming denial of motion to amend to assert fraud defense "that would have raised new issues, which were not involved in the case during discovery and were not the subject of Plaintiff's discovery and trial preparation); *MacDraw, Inc. v. The CIT Group Equipment Financing, Inc.*, 157 F.3d 956

(2d Cir. 1998) (no abuse of discretion in denying motion to amend which would have prejudiced the defendants by adding a claim more than five years after filing the complaint); *Mercantile Trust Co. v. Inland Marine Products Corp.*, 542 F.2d 1010, 1013 (8th Cir. 1976) (no abuse of discretion where district court refused to allow late amendment which would add new theories of defense and which "would necessarily reopen much of the discovery"). In particular, courts will not allow belated amendments intended to avoid the consequences of dispositive motions, especially when the attempted amendment changes the factual basis of a claim. *See Sandcrest Outpatient Services, P.A. v. Cumberland County Hosp. Sys., Inc.*, 853 F.2d 1139 (4th Cir. 1988); *Overseas Inns S.A. P.A. v. U.S.*, 911 F.2d 1146 (5th Cir. 1990); *Addington v. Farmer's Elevator Mut. Ins. Co.*, 650 F.2d 663 (5th Cir.), *cert. denied*, 454 U.S. 1098, 102 S. Ct. 672, 70 L. Ed. 2d 640 (1981); *Glesenkamp v. Nationwide Mut. Ins. Co.*, 71 F.R.D. 1 (N.D. Calif. 1974), *aff'd*, 540 F.2d 458 (9th Cir. 1978).

The Fourth Circuit reviewed the District Court's decision denying the Petitioners' motion for leave to amend their Complaints under an abuse of discretion standard. *See Foman*, 371 U.S. at 182, 83 S. Ct. at 230. The Fourth Circuit agreed with the District Court that the Petitioners' motions to amend were primarily intended to thwart Respondents' motions for Summary Judgment. Secondly, the Fourth Circuit agreed that it would have been unfair to allow Petitioners the right to amend their Complaints to change the theory of their cases after extensive discovery had already been conducted especially in light of the fact that Petitioners had known of the presence of substances other than picloram in the Gold Dollar fertilizer since the earliest stages of this now very old case. Consistent with

the Fourth Circuit's earlier decision in *Sandcrest*, *supra*, the Fourth Circuit chose not to allow Petitioners to attempt to change the character of the litigation at a late and dispositive stage. Petitioners provide no explanation for the grounds upon which any court could find that the denial of these motions were an abuse of the District Court's discretion.

### 3. No other compelling reasons exist to justify a Writ of Certiorari.

*Daubert* has become part of the lexicon of American jurisprudence and a daily fact of life for trial judges across the country. The amendments to Rule 702 implemented in 2000 have institutionalized the factors to be considered by trial courts in carrying out their gatekeeping function. Other than the fact that the case at bar dealt with picloram and fertilizer, the process of evaluating an expert's reliability in this case did not differ from the process of evaluating an expert in any other case. Granting a Writ of Certiorari to evaluate this case would add nothing further to the Court's current *Daubert* jurisprudence.

The Fourth Circuit did not depart from the accepted and usual course of judicial proceedings, nor did it sanction such behavior on the part of the District Court. The Fourth Circuit's analysis of the District Court's actions was routine. The Court's analysis of the District Court's procedure tracked the language of *Daubert* almost word for word. The Petition makes no suggestion to the contrary. Rather, the Petition contains page after page of irrelevant and redundant material that does not bear on the central issue of whether Levin's methodology as revealed through his testimony before the District Court

at the time of Respondent's motions for Summary Judgment was admissible.

Nothing distinguishes the outcome of this case from other ordinary tort actions without proof of proximate cause. The Petition seeks to inflame the Court by repeatedly making reference to the deaths of two individuals and enormous jury verdicts in other cases, but none of those allegations bear on the admissibility of Petitioners' alleged proof of proximate cause. Nor is there anything to distinguish this case from the innumerable other cases addressing whether a motion to amend a complaint should be allowed. The rulings of the District Court in this were discretionary, which by their very nature are designed to give broad latitude to lower courts. The case was carefully considered at the trial level and by the Fourth Circuit, and no reason has been proffered to disturb those rulings.

## CONCLUSION

For the reasons stated herein, Respondents respectfully request that the Court deny the Petition for Writ of Certiorari.

Respectfully submitted this the fourth day of June, 2004.

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